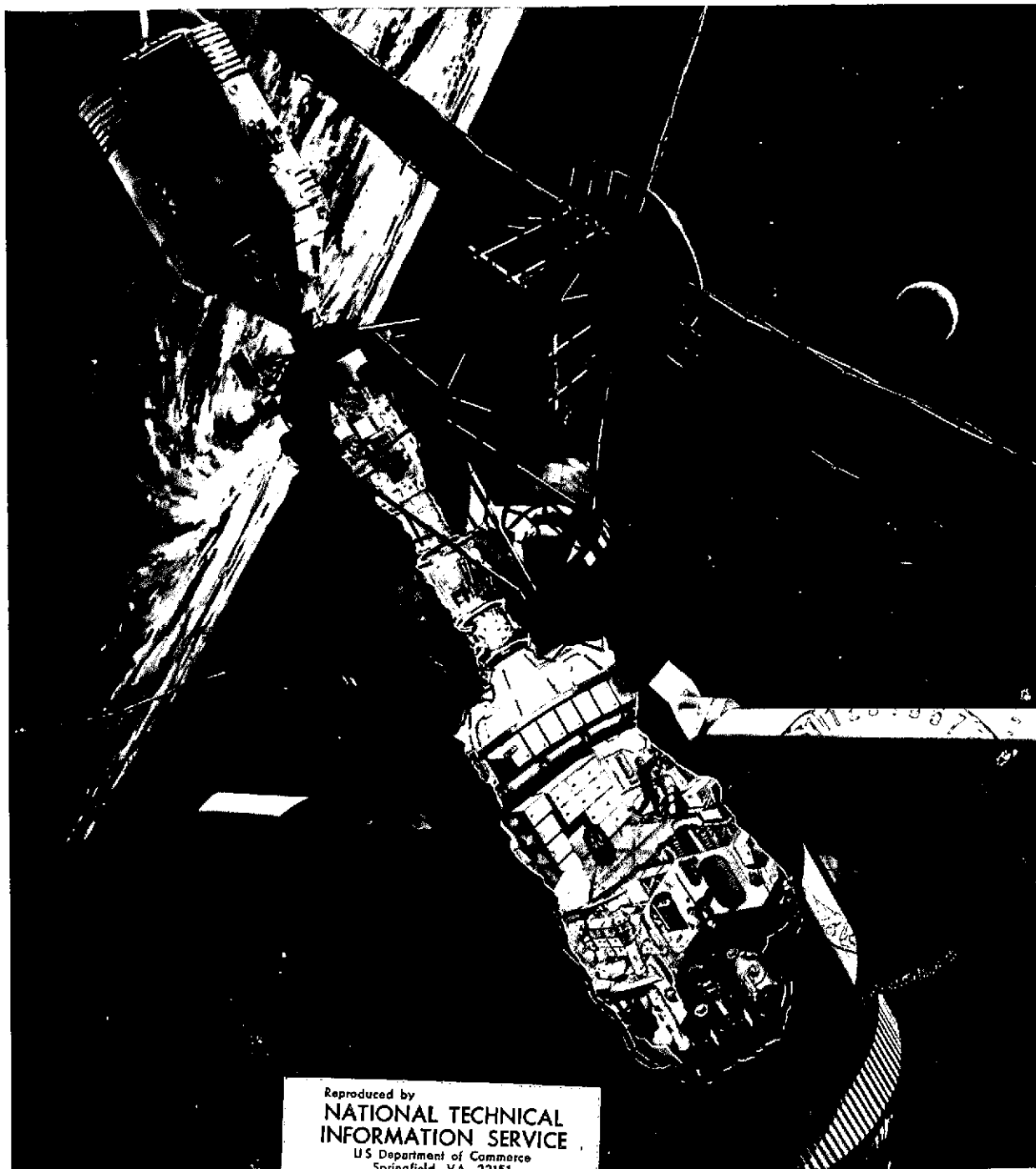


Cardiology

A Case Study of Technology Transfer



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A CASE STUDY OF TECHNOLOGY TRANSFER:
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The technology reviewed in this document and the applications noted represent the best knowledge available at the time of preparation. Neither the United States Government nor any person acting on behalf of the United States Government assumes any liability resulting from use of the information contained in this document, or warrants that such use will be free from privately owned rights.

ABOUT THE COVER

The Skylab biomedical program is a study of normal, healthy men and their reactions to a zero gravity environment. Of vital interest to the area of cardiology are the experiments to determine the effects of long exposure to zero gravity on the heart and blood vessels.

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A CASE STUDY OF TECHNOLOGY TRANSFER:

CARDIOLOGY

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- Prepared by -

Gerald Schafer
Industrial Economics Division
Denver Research Institute
University of Denver

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A CASE STUDY OF TECHNOLOGY TRANSFER: CARDIOLOGY

On October 24, 1971, during the Chicago Bears-Detroit Lions National Football League game, the Lion's wide receiver suffered an injury late in the fourth quarter. The backup man, Chuck Hughes, entered the game with about ten minutes to play. With less than two minutes remaining, Hughes hauled in a thirty-two yard pass from quarterback Greg Landry and was immediately brought down in a crushing tackle by two Bears defenders. It was his first pass reception of the season. Two plays later, he returned to the huddle after running a deep pass pattern. It was the final huddle for Hughes. As the next play was being called, Hughes suddenly clutched his chest and toppled face down on the turf. An hour later, he was pronounced dead at Henry Ford Hospital (New York Times, October 25, 1971 and Newsweek, November 8, 1971).

An autopsy revealed that Hughes had suffered an attack of arteriosclerosis--an acute coronary thrombosis, a heart attack. Physicians for the Detroit Lions said that the arteriosclerosis heart disease had been coming on for some time, with no signs. The disease is characterized by abnormal thickening and hardening of the arterial walls, eventually shutting off the blood flow to the heart. This hardening of the arteries had severely restricted Hughes' blood flow. Since the disease often cannot be easily detected, Hughes probably was not aware of it. In fact, he had been hospitalized with pains after being tackled hard in a pre-season exhibition game, but a cardiogram, an arteriogram, and other laboratory tests revealed nothing. Before playing against the New England Patriots on September 26, Hughes was quoted as saying:

I don't know what's wrong, I've had sharp pains in my stomach and my chest and they've made all sorts of tests, but nobody seems to be able to figure them out. I want to play though. They aren't that bad (New York Times, October 26, 1971).

This story is unusual because Chuck Hughes was only twenty-eight years old and a professional athlete in top physical condition. It is not unusual, however, when one considers that each year in the United States more than 840,000 persons die of arteriosclerosis (National Heart and Lung Institute, National Program, 1973) and at least 250,000 persons are victims of sudden heart failure (U. S. News & World Report, September 18, 1972).

An Overview of Cardiology

Cardiology, the study of the healthy and diseased heart and blood vessels, has a history as old as man's interest in his own bodily functions. Written records from the early days of the Greek Empire document this interest, although it is certain that earlier civilizations, such as the Egyptians and Mesopotamians, possessed much knowledge which probably influenced the Greeks. The greatest of the Greek works on the heart and circulatory system, On Anatomical Procedures, was compiled by Galen in the second century, A. D. (Baldry, 1971). His teachings were accepted as an accurate account by Christian, Jewish and Moslem theologians. This acceptance sanctified the ideas proposed to such an extent that any attempt to challenge or contradict them was considered blasphemous and heretical.

Thus, study of the heart evolved quite slowly until 1543 when Andreas Vesalius published Humani Corporis Fabrica, an attack of Galen's theories (Baldry, 1971). Thereafter, with the coming of the Renaissance, more and more accurate knowledge, such as Harvey's description of the circulatory system, began to appear.

Still, it was not until late in the nineteenth century that cardiology became recognized as the field it is today. The first heart surgery, in 1895, opened a whole new frontier. Slowly, heart surgery became accepted in medical practice; more venturesome operations, such as the first successful ligation of the congenital anomaly, patent ductus arteriosus, by Dr. Robert Gross in 1939, were undertaken.

Today, heart surgery has progressed by such miraculous bounds that even open-heart surgery is commonplace in modern hospitals. Several factors are responsible for the successful operations now being performed:

- More delicate, highly specialized tools and materials developed for actual cutting and repair, or substitution, of heart and artery tissue;
- Improved diagnostic tools;
- More sophisticated equipment for blood analysis;
- Improved methods of administering anesthesia;

- Advances in heart-lung machines, making them more responsive to patient needs; and
- New post-operative techniques for monitoring vital functions (U. S. News & World Report, September 18, 1972).

Cardiovascular Research

Cardiovascular disease is the number one killer in the United States, accounting for more than one million deaths a year. In 1970, for example, cardiovascular disease accounted for 52.5 percent of all deaths in the United States; in comparison, cancer, the number two killer, accounted for only 17.2 percent and motor vehicle mortalities for only 2.7 percent (U. S. Department of Commerce, 1972). It is estimated that fifteen million Americans between the ages of eighteen and seventy-nine suffer from heart disease, with about two million of those becoming seriously handicapped (Science Digest, April 1972). In addition, cardiovascular disease is estimated to cost more than thirty billion dollars annually in lost wages, lost productivity and in medical expenses. If heart and blood vessel disease could be eliminated, it would mean an increase of almost eleven years in the average life expectancy in this country ("National Heart, Blood Vessel, Lung and Blood Act of 1972," September 19, 1972).

The view of cardiovascular research today is essentially the same as that of twenty years ago, as exemplified in the following statements:

Important discoveries about heart disease, now being made, are expected before long to save the lives of thousands of people in this country. A flood of new leads, hotly pursued in laboratories all over the United States, is beginning to produce some of the answers to heart and circulation diseases that kill 700,000 people in the U. S. every year (U. S. News & World Report, September 14, 1951).

The biggest push yet to unlock the mysteries of heart attacks is now underway. Funded by a \$14 billion, three-year federal grant, it will focus on both basic and clinical research, on long-range prevention as well as cure The new offensive is necessary

because the stubborn enemy has not yielded an inch in 20 years. Despite all the publicity about transplants and all the warnings about exercise, smoking, diet and stress, heart attacks still fell a million persons a year, nearly 700,000 of them fatally--the same death rate as in 1950 (Today's Health, February 1973).

These statements reflect the quandary in which those conducting heart research find themselves. The growing battle against heart disease can be traced by examining the yearly appropriations of the National Heart and Lung Institute (see Figure 1). Efforts and money have increased, and, yet, the long awaited "breakthroughs" have not appeared.

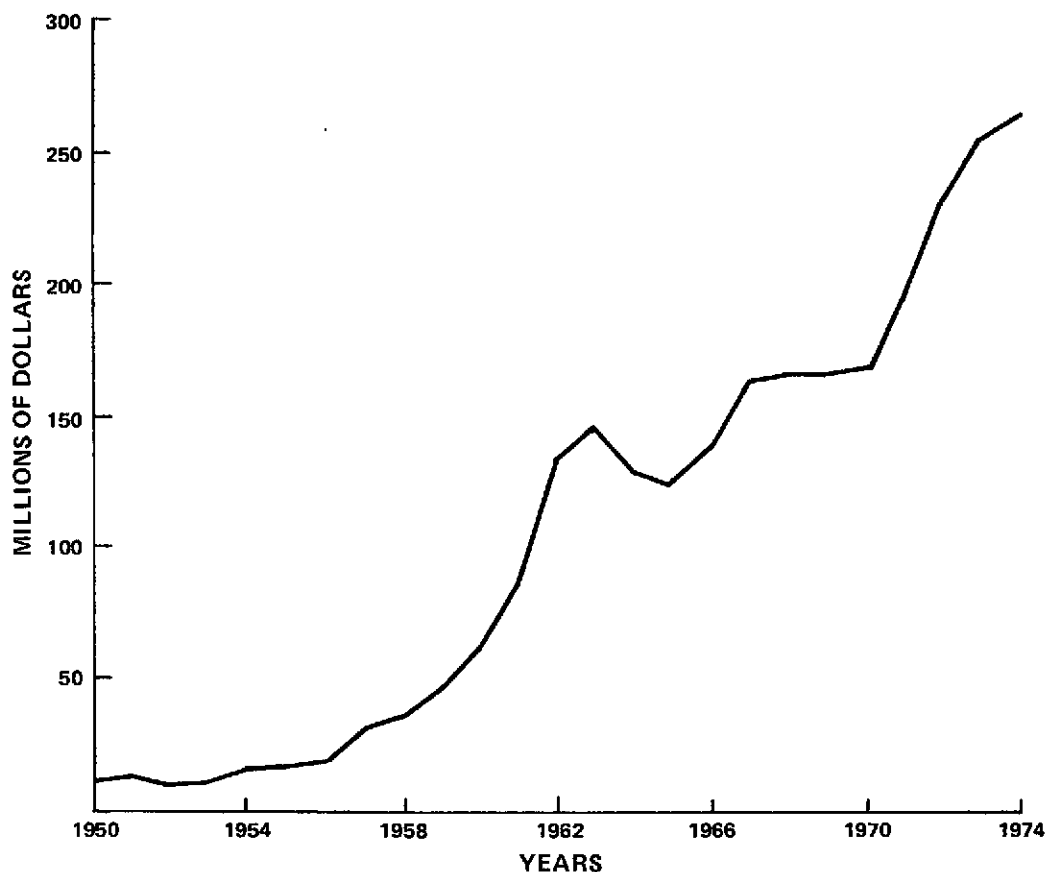


Figure 1. National Heart and Lung Institute Appropriations, FY 1950 - 1974. [Source: National Heart and Lung Institute, 1973.]

It would be extremely inaccurate, however, to say that no progress has been made. Advances are continually emerging from the laboratories and hospitals, indicating that eventually the problem of heart disease can be controlled. Some of these advances are:

- Safely removing blood clots, either by cutting or reaming;
- "Blowing out" harmful masses of fatty tissue by introducing gas under pressure into an artery;
- Using new synthetic materials to patch weak places in arteries;
- Bypassing plugged or weakened arteries with new artificial substitutes, or with blood vessels from other parts of the body;
- Replacing malfunctioning heart valves with long-lasting artificial substitutes, or with human transplants;
- Installing electrically powered pacemakers for hearts with weak, erratic beats;
- Using drugs to increase or improve blood flow; and
- Inserting intra-aortic balloon pumps, which assist circulation by inflating and deflating when damaged heart muscles fail (U. S. News & World Report, September 18, 1972 and Good Housekeeping, May 1972).

The future of cardiovascular research is unlimited. Two of the most promising developments could be the artificial heart and the use of preventative drugs which reduce fatty substances in the blood, particularly cholesterol. Along with these, the development of a noninvasive technique of detecting arteriosclerotic changes in vessels is being sought so that progression of the disease can be traced (Science, September 7, 1973).

Government participation. The Congress of the United States recognized the need for expanded and directed cardiological research by enacting the "National Heart, Blood Vessel, Lung and Blood Act of 1972." This act gives the National Heart and Lung Institute the authority to coordinate the research activities of all government agencies in the areas of cardiology, pulmonary function and hematology. The Institute's four primary goals are to promote health, prevent disease, treat disease and restore health. The overall strategy for the National Heart, Blood Vessel, Lung and Blood Program is depicted in Figure 2.

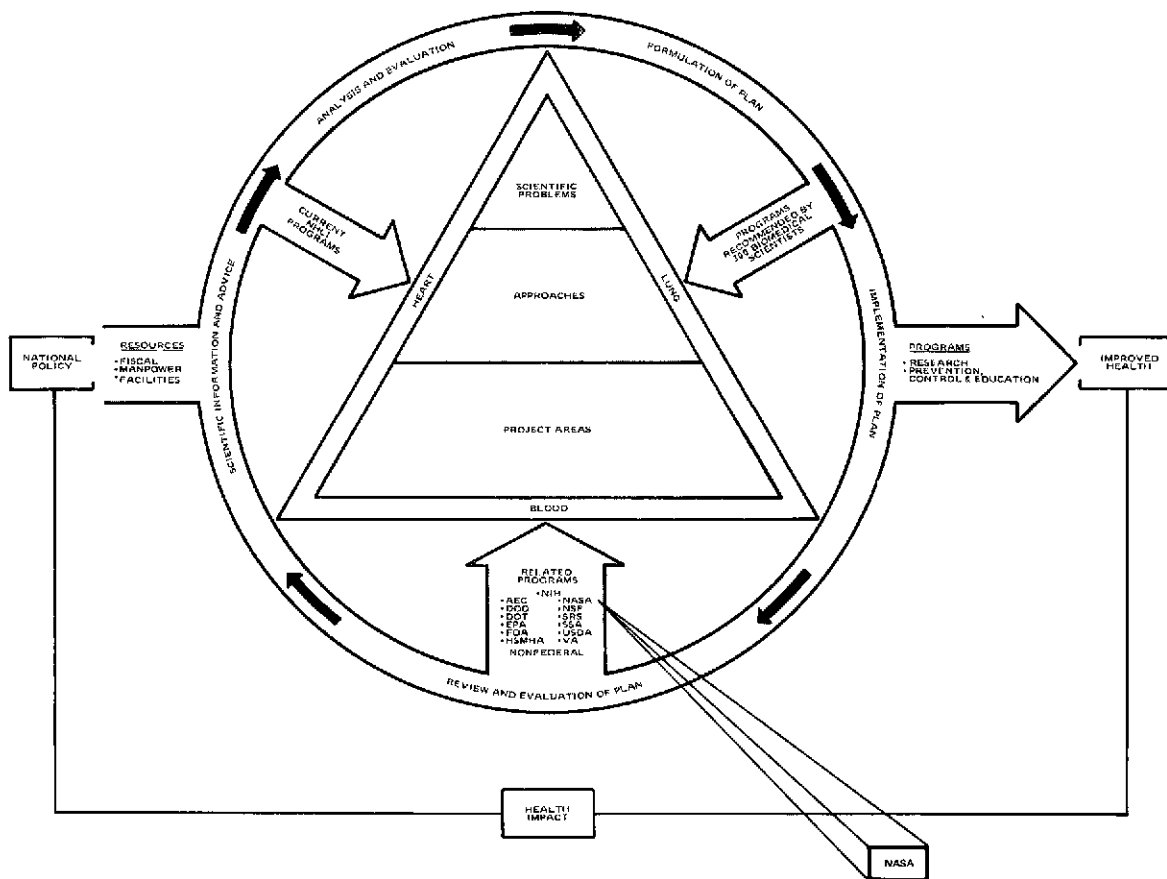


Figure 2. National Heart, Blood Vessel, Lung and Blood Program Strategy. [Source: National Heart, Blood Vessel, Lung and Blood Program, 1973.]

Four major groups have been recognized as contributing to the research activities of this national program: (1) the National Heart and Lung Institute; (2) other institutes and divisions of the National Institutes of Health; (3) federal agencies exclusive of the National Institutes of Health;* and (4) voluntary organizations. As one of the federal agencies carrying out specific research in the area of heart and blood vessels, the National Aeronautics and Space Administration has contributed in a substantial way to the basic knowledge of cardiology.

The NASA role. The National Heart and Lung Institute recognizes that:

NASA supports related mission-oriented research directed at understanding, measuring, and controlling body functions and mechanisms in diverse environmental states. Instrumentation and techniques have been and are being developed directly applicable to the cardiovascular and pulmonary systems (National Heart and Lung Institute, 1973).

An inventory of NASA-supported research projects in the area of cardiology has been compiled by the National Heart and Lung Institute and is summarized in Table 1. An examination of these projects reveals why NASA's research is so uniquely important: NASA is one of the few agencies carrying out research that concentrates on studying the normal or healthy heart. The vast majority of all other cardiological research involves studying the diseased circulatory system. It is necessary, however, to advance knowledge concerning the physiology and function of the normal circulatory system in order to develop a better understanding of the diseased one (Johnson, 1973).

* Department of Agriculture, Atomic Energy Commission, Department of Defense, Environmental Protection Agency, Food and Drug Administration, Health Services and Mental Health Administration, National Aeronautics and Space Administration, National Science Foundation, Social and Rehabilitation Service, Social Security Administration, Department of Transportation and Veterans Administration.

TABLE 1. PROGRAM ANALYSIS - NATIONAL AERONAUTICS
AND SPACE ADMINISTRATION - FISCAL YEAR 1972*

RESEARCH PROJECTS
<ul style="list-style-type: none">• Advanced cardiovascular bioinstrumentation in man• A feasibility study of a microwave regional blood volume sensing technique• Noninvasive measurement of central venous pressure• Ultrasonic Doppler measurement of renal artery blood flow• Study for vectorcardiogram display system and blood pressure monitoring systems• Feasibility study of limb volume measuring systems• Neurohumoral control of cardiovascular responses• Regulation of blood flow distribution• Biocybernetic model of the cardiovascular system during headward and footward acceleration• Studies of left ventricular function and vasodepressor syncope• Investigation of atraumatic techniques for monitoring cardiovascular status and conditioning• Cardiovascular hemodynamics in man• Control of vascular distensibility• Effects of space flights on vascular permeability

* Source: National Heart, Blood Vessel, Lung and Blood Program, 1973.

NASA also serves the advancement of cardiological research by providing impetus to the medical community. The demands of the aerospace program, such as prolonged weightlessness, required that knowledge of basic human physiology be rapidly expanded. Thus, it is estimated that such knowledge is at a more advanced level than if the aerospace program had not existed (Leach, 1973).

Selected NASA Contributions to Cardiology

Activities of the National Aeronautics and Space Administration in the area of cardiology have come about because of the declared mission of the Space Life Sciences Program "to keep man alive and in good functional order and to support and aid him as he operates under the physical stresses of the space environment" (U. S. Congress, House, 1973). These activities consist mainly of furthering man's knowledge of basic human physiology and developing instrumentation and techniques for monitoring vital life signs.

In the area of understanding basic human physiology, much of the work is performed at American universities and colleges under NASA-supported research grants. For example, one such program at Harvard Medical School involves the study of renal blood flow. Some of these grants relate directly to NASA's primary mission objectives while others serve to provide scientific knowledge--knowledge that is important for a better understanding of man's functions and vital processes, if not directly applicable to space flight (Johnson, 1973).

In attempting to understand how man reacts in a zero-gravity space environment, NASA has developed instrumentation and techniques devised to monitor vital functions on earth as well as in space. Development of instrumentation applicable to cardiology is a role of great significance. At a National Academy of Engineering symposium on "Engineering and Medicine," Dr. James V. Maloney, Chief of the Thoracic Surgery Division and Professor of Surgery, University of California at Los Angeles School of Medicine, declared that:

. . . the contributions to human health and welfare that are going to be made by engineering in the next 5 years will be as great or perhaps greater than the contributions of any individual specialty within the biological sciences (National Academy of Engineering, 1970).

NASA's work in bioinstrumentation consists mainly of advancing the development of existing, but unsatisfactory, instrumentation (Fryer, 1973). As observed:

Measurement instruments are now available for nearly all physiological diagnostic indexes presently considered useful by the medical profession. Pertinent data can be acquired and transmitted reliably and conveniently almost anywhere. There is a need to enhance the speed, accuracy, precision, and economy of treating these measures and to extend their application on a community-wide basis (National Academy of Engineering, 1970).

And, it is in response to this need that NASA is contributing to the field of cardiology.

Throughout the remaining portion of this document, examples of selected NASA contributions to cardiology are discussed. While some of these illustrate the manner in which the generation of technology, either instrumentation or techniques, provides new alternatives and focus for professional progress, others are illustrative of the application of technology to specific problems confronting the medical community.

Electrode technology. Electrocardiography has found increasing use since its invention in 1903 by William Eithoven. Since the electrocardiogram (EKG) is an excellent means of determining heart muscle activity such as disturbances of rhythm (arrhythmia), damage to the heart muscle, imbalance between the two sides of the heart where one side is overloaded, and various kinds of poisoning that affect the heart muscles (e. g. , digitalis or potassium), NASA has used it to monitor and observe astronauts during training and in space flight.

The EKG is the record of electrical changes in the heart muscle. The very weak electrical signals produced by the heart are detected by electrodes placed on the body. These signals are then relayed to a device which amplifies and records them. The electrode has been the major problem-causing mechanism of taking EKG's. There are basically two difficulties: (1) the electrode must be able to pick up the heart's weak electrical signal with little disturbance or artifact noise, and (2) the electrodes must be comfortable so that they may be worn for great lengths of time.

Because monitoring the EKG is such a basic and necessary task, NASA has put great effort into developing electrode technology. Even though the electrocardiogram had been in clinical use for more than fifty years, it was discovered during preparation for the Mercury Program that no existing electrodes were acceptable for space flight. This was mainly due to the electrode paste, or electrolyte, which caused skin irritation and dried out, thus losing its conductivity and effectiveness (Jones, 1966). The need for acceptable electrodes thus produced a series of advances in electrode technology that can be illustrated by examining the NASA Tech Briefs* describing them:

- Improved Electrode Gives High-Quality Biological Recordings (TB 64-10025)
- Improved Conductive Paste Secures Biomedical Electrodes (TB 65-10015)
- Rugged Pressed Disk Electrode Has Low Contact Potential (TB 65-10320)
- Improved Electrode Paste Provides Reliable Measurement of Galvanic Skin Response (TB 66-10049)
- Gelatin-Coated Electrodes Allow Prolonged Bio-electronic Measurements (TB 66-10055)
- Integrated Skin Electrode for Electrocardiography is Expendable (TB 66-10118)
- Spray-On Electrodes Enable ECG Monitoring of Physically Active Subjects (TB 66-10649)
- Quick Don-Off Electrode Pastes (TB 69-10598)
- Ultra-Flexible Biomedical Electrodes and Wires (TB 70-10420)
- Improved Biomedical Electrode (TB 72-10642)
- A New Dry Biomedical Electrode (TB 73-10146)

* One of the mechanisms used by the NASA Technology Utilization Office to acquaint industry and the public with the technical content of an innovation derived from the space program.

Since satisfactory signal detection has been achieved, electrode technology has reached a point where research is now concentrated on skin compatibility and wearer comfort (Rositano, 1973). For instance, research being conducted at NASA Ames Research Center is directed toward new electrodes that may be worn for extremely long periods of time with minimum skin irritation or wearer discomfort. One experiment, done in conjunction with bedrest studies at Ames, involves the use of conductive knit mesh electrodes. The results appear to hold great promise as the electrodes have been worn for extended periods with no signs of skin irritation and very little inconvenience or discomfort to the subjects. Development of electrodes such as these that can be worn for long periods of time with no ill affects have direct implications for clinical application with patients requiring constant and long-term care.

The real-time contourograph display system. Electrocardiograph results, or tracings, traditionally have been displayed either on a continuous paper strip or by single beats appearing on a cathode ray tube similar to a television screen. The former method typically produces miles of paper that must be manually scanned for interpretation, while the latter provides no means of comparison since only one beat is visible at any given time.

A new approach to monitoring EKG signals, contourography, was developed by George N. Webb and Richard E. Rogers (Webb and Rogers, 1966 and Webb, 1974). Contourography is a technique for presenting repetitive data in a highly informative manner. In effect, contourography stacks succeeding cycles of data one below the other. This makes any major change in the data immediately apparent in the overall contourogram pattern. Electrocardiograph tracings lend themselves to contourographic format because each cardiac cycle, or heartbeat, has a characteristic waveform (Wolthuis, 1973).

A contourograph device displaying a continuous, real-time EKG contourogram was developed by Technology, Incorporated, under contract to the NASA Lyndon B. Johnson Space Center (Golden, 1970). This real-time contourograph system has several important advantages over previous systems of monitoring electrocardiograms, including:

- The EKG contourogram is generated continuously, in real-time, so that instantaneous heart rate can be read directly from the cathode ray tube, as can any conspicuous variation in the EKG pattern.

- The system permits three different viewing modes, including a standard clinical EKG display (single beats only appearing).
- To a trained observer, the system presents a great deal of information in an extremely concise form.

Because the real-time contourograph allows constant monitoring and quick identification of variations in the EKG, it is being used successfully to monitor astronauts while in flight and during pre- and post-flight tests.

Technology, Incorporated, recognizing the potential market value of the real-time contourograph, is currently performing market studies for the commercialization of a slightly modified version of the NASA instrument (see Figure 3). Intended for cardiac monitoring, the system would have two potential applications: direct patient monitoring, such as in an intensive care unit; and the playback of recorded EKG data, enabling a physician to analyze hours of data in minutes (Pugh, 1973).

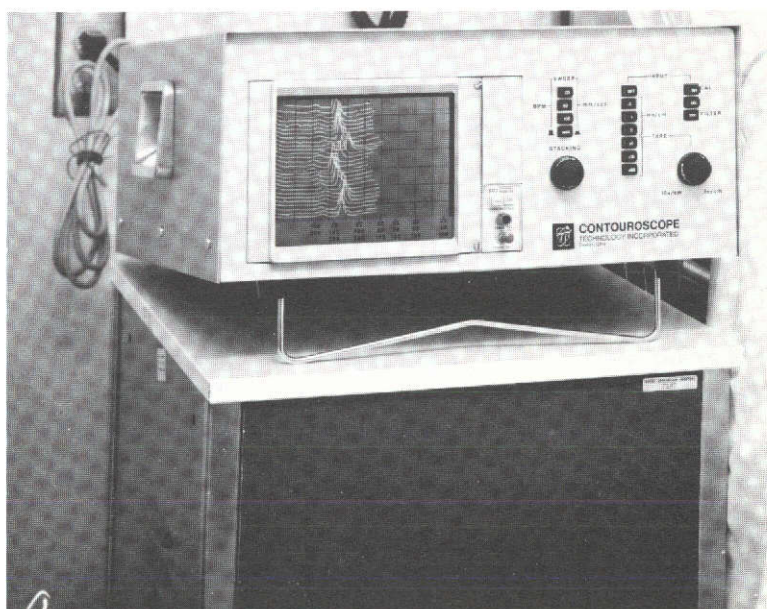


Figure 3. The Real-Time Contourograph Display System.

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Detecting arteriosclerotic changes in blood vessels. As part of the National Heart, Blood Vessel, Lung and Blood Program, the National Heart and Lung Institute has established several Arteriosclerosis Specialized Centers of Research. Since there has been no noninvasive means of accurately detecting arteriosclerotic changes in vessels, one effort being undertaken by these Centers is the development of instrumentation to diagnosis and characterize athrosclerotic plaques (National Heart and Lung Institute, National Program, 1973).

The Specialized Center of Research at the University of Southern California is conducting a study to determine the effects of diet, exercise, and other factors on the buildup of cholesterol in blood vessels. As part of this study, a noninvasive technique to monitor changes in vessel roughness and plaque buildup was needed.

The Jet Propulsion Laboratory (JPL), working with the University, is developing such a technique utilizing digital computer processing of X-ray photos, a process derived from technology developed at JPL to correct distortions in images received from the television cameras of the Ranger, Mariner, and Surveyor spacecraft (Selzer, 1966). * The technique is entirely noninvasive, except for the injection of a dye into the blood stream. After the dye is injected, X-rays are taken and processed using the enhancement technique (Selzer, 1974). They are then examined to determine plaque buildup and vessel roughness.

The development of this technique to monitor changes in the blood vessels is of vital importance to continued research on the effects of cholesterol. In this way, it is also instrumental in clarifying the role of personal habits, such as diet and exercise, in arteriosclerotic heart disease.

* This is yet another application of the process which is already finding application in the medical community for automating the calculation of left-ventricular blood volume; detecting more accurately the beginnings of cancer and other abnormalities and disfunctions; analyzing tooth X-rays; and processing photos of chromosomes. These applications are in addition to those occurring outside the medical community, such as the inspection of printed circuit boards.

Automated blood pressure measuring system. "The measurement of blood pressure in the human body is probably the most widely used diagnostic tool in the practice of medicine today" (Smith, 1964). To the physician, blood pressure measurement can reveal malfunctions of the heart and substantiate diseases of the blood-carrying ducts, such as arteriosclerosis and congenital cardiovascular anomalies. In addition, many other organic ailments, pulmonary and endocrine disorders, and disorders of the nervous system can manifest themselves in blood pressure variations (Smith, 1964).

The most common method of measuring blood pressure is by using a sphygmomanometer, a well-known instrument that consists of a column of mercury supported by the air pressure in an inflatable cuff. The cuff is wrapped around a limb and inflated. When the pressure is just enough to obliterate the pulse, the height of the column of mercury indicates the systolic blood pressure (the pumping or active phase of the heartbeat). When the pressure in the cuff is reduced to the diastolic blood pressure (the resting or passive phase of the heartbeat), a slapping sound is heard over the artery beyond the cuff. These characteristic sounds are called Korotkov sounds, or K-sounds, for the man who first detected them.

NASA's Project Skylab scheduled several experiments that required an automated, noninvasive system for blood pressure measurement. The system had to meet four requirements in measuring blood pressure: (1) at rest and during stress procedures; (2) before, during, and after exercising; (3) in normal and zero gravity environments; and (4) with an accuracy equal to accepted clinical techniques (Wolthuis, et al., 1971).

After an examination of various types of blood pressure measurement techniques, researchers chose to adapt the Korotkov sound technique for implementation into the system. This decision was made because of the K-sound's clinical and historical precedence, adaptability to automation, and relative insensitivity to motion-caused artifact, or interference, as compared to ultrasonic techniques.

The system developed consists of an arm cuff which is rapidly inflated to a pressure sufficient to stop blood flow to the forearm, and then it is slowly depressurized. During this depressurization, the Korotkov sounds are picked up by a microphone placed under the cuff,

amplified, and then fed to a processor and decision logic system (see Figure 4). The product of this decision logic system is the systolic and diastolic blood pressures being displayed on a digital readout mechanism.

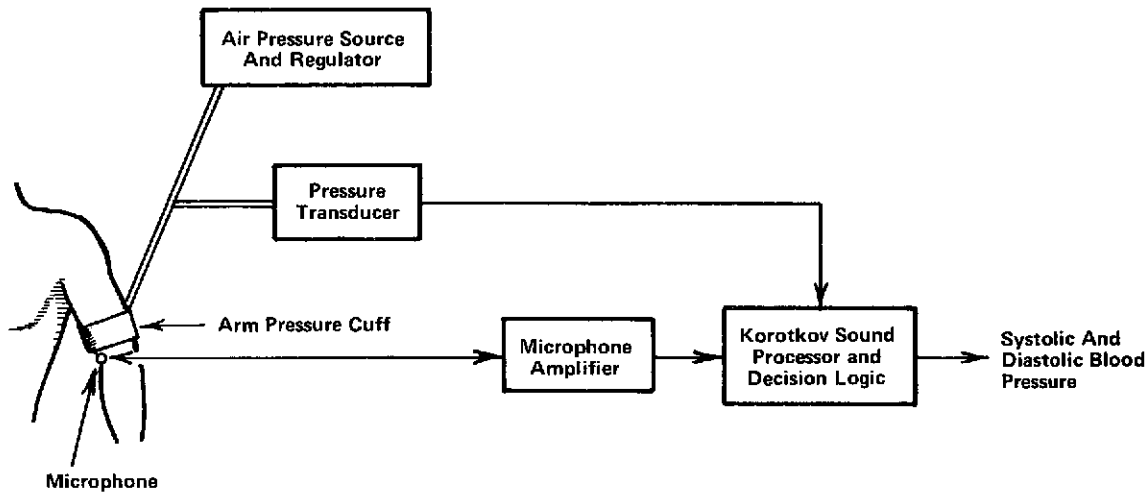


Figure 4. Automated Analysis of Blood Pressure Measurements.

This automated blood pressure measurement technique has been adapted by SCI Systems, Incorporated, under contract to the Lyndon B. Johnson Space Center, and is now being marketed as part of their TELECARE Emergency System (Castle, 1973). TELECARE is a unit that has, in one package, all the components that could reasonably be used in an acute cardiopulmonary situation. It contains: a respiratory resuscitation system; a fifteen-minute oxygen supply derived from a chlorate candle developed from space technology; an electrocardiogram display and telemetry system; a defibrillator for external heart stimulation; and the blood pressure measurement system similar to that developed for Skylab, which can frequently be used in many situations where there is high background noise or when the patient is in shock, which diminishes Korotkov sounds. TELECARE units are now being used in twenty-eight rescue vehicles in Houston, Texas (see Figure 5).

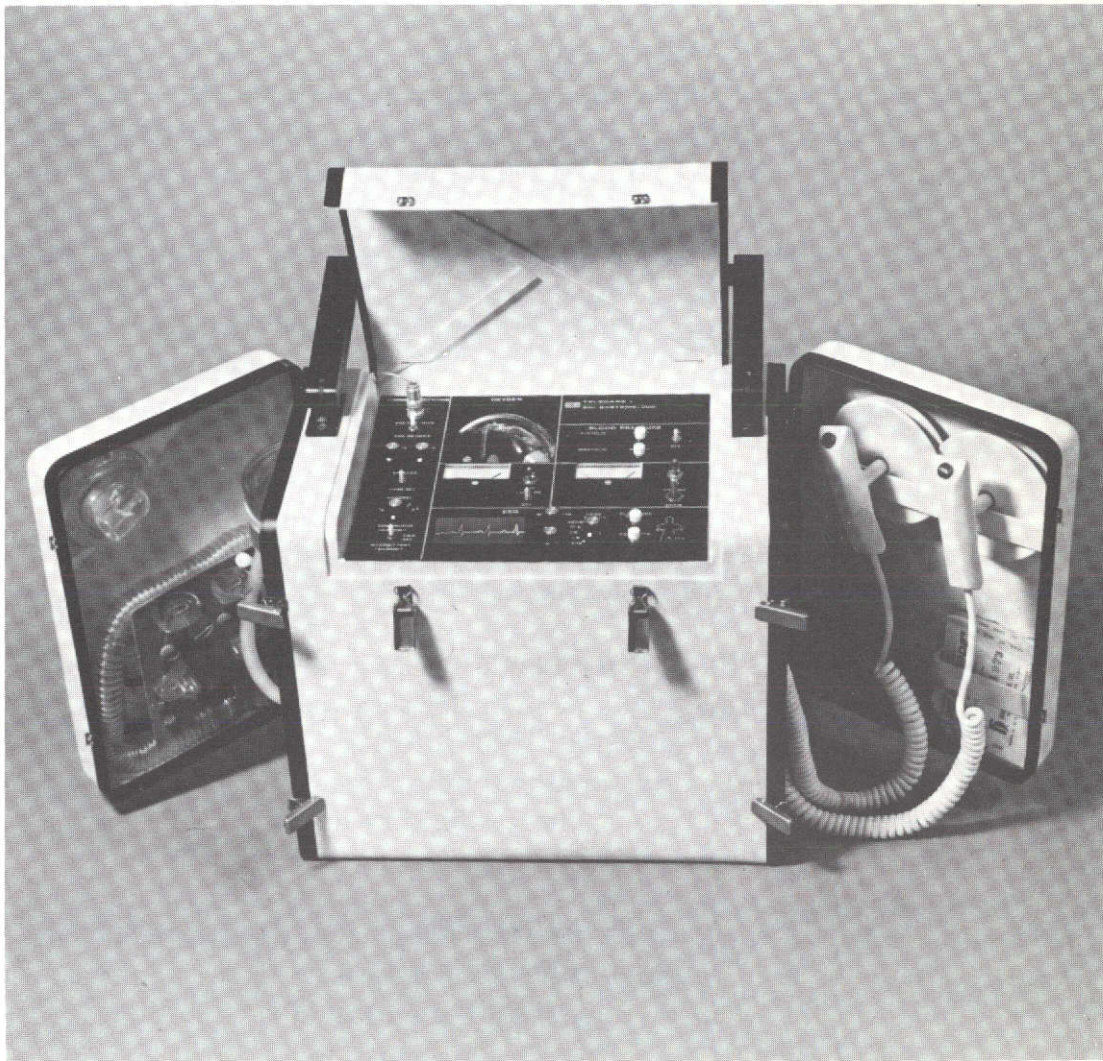


Figure 5. The TELECARE Unit.

NASA Biomedical Application Teams. In 1966 the NASA Technology Utilization Office established a program using an active and directed methodology for the dissemination and utilization of technical information. Interdisciplinary teams of scientists were formed to bridge the communication gap between the developers and users of technology. Of special interest to the area of cardiology are the efforts to bring together NASA's physical scientists and the medical world. For this purpose, Biomedical Application Teams have been established. Each team consists of individuals in the biological and physical sciences who are practicing, informed, and who can communicate readily across interdisciplinary lines. All are equipped with

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firsthand knowledge of areas of active research at NASA and contractor facilities and are familiar with NASA's collection of technical information. In short, the teams represent a specialized human link between NASA, its research centers and contractors, and the biological and medical communities (Castles, 1971). This relationship is carried out to whatever extent the situation demands, short of performing the actual operations for the potential user. For example, information alone may suffice the medical researcher, while a medical practitioner may need assistance in experimental design, interpretation of aerospace technology, or help in applying for funds to accomplish his goals.

NASA's Technology Utilization Office has three Biomedical Application Teams presently in operation. These are located at the Research Triangle Institute, Durham, North Carolina; Southwest Research Institute, San Antonio, Texas; and Stanford University School of Medicine, Palo Alto, California.

The team at Stanford University School of Medicine, Cardiology Division, is of special interest because it directs primary emphasis toward the identification, acquisition, and solution of research and clinical problems in the area of cardiovascular medicine. The approach used at Stanford involves a close working relationship, on a few in-depth studies, between scientists and engineers at NASA Ames Research Center and physicians and engineers of the team (Stanford University School of Medicine, 1973). It is hoped that by working on a few detailed studies, the Stanford team can make significant contributions to the area of cardiology using NASA-developed technology.

The ultrasonoscope. For a patient, the use of noninvasive techniques for diagnosis of illness has obvious advantages over invasive techniques, or those that require penetration of the body. The trauma, both physical and emotional, that occurs with invasion can be extremely detrimental. For the physician and engineer, noninvasive techniques present a special problem that is analogous to a television repairman trying to troubleshoot a TV without opening the cabinet (Fryer, 1973). Ultrasound is one technique now being explored that has great potential in the area of noninvasive diagnosis.

In an ultrasonoscope, the instrument used for ultrasound studies, an ultrasonic transducer emits a signal that travels through the skin and chest wall to the heart, is reflected from the front and back walls of the heart, and travels back to the same transducer. The signal

echoes are then processed so that a quantitative readout of information concerning heart size and volume can be calculated (U. S. Congress, House, 1973). Ultrasound has been shown clinically useful in the diagnosis of aortic, mitral and tricuspid valve disease, foreign bodies in the heart, the presence of pericardial effusion, and specific congenital heart defects (Stanford University School of Medicine, 1972).

During an active program of ultrasonic diagnosis at Stanford University Hospital, it was found that commercially available equipment was bulky and was potentially hazardous from an electrical shock standpoint, especially when used with electrically sensitive patients such as those found in a cardiac catheterization laboratory or in a newborn nursery (Stanford University School of Medicine, 1973). Thus, Robert Lee of the NASA Ames Research Center and Dr. Richard Y. Popp at Stanford University are refining the ultrasonoscope used for noninvasive study of the heart.

The prototype now being tested has been reduced in size so that it is highly mobile and easily transported to the bedside or the cardiac catheterization laboratory. Also, it has been independently tested to ensure its electrical safety--a point of paramount concern in medical instruments and a major advantage of the NASA-developed ultrasonoscope.

The device has been used at Stanford in the newborn nursery and the pediatric ward where patients are housed in a controlled environment, often in Isolettes that have other electrical systems for controlled temperature and humidity. In addition, patients are usually monitored with other externally powered instrumentation. Since it is not feasible to disconnect all of this equipment during an ultrasonic examination, dangerous leakage currents can be transmitted through the heart and body if multiple alternating current devices are used simultaneously. The NASA battery-operated ultrasonoscope completely avoids this hazard, and ultrasonic information can safely be obtained while life-support systems continue (Stanford University School of Medicine, 1973).

Additional clinical evaluation studies are being carried out at Stanford, and the diagnostic quality of the prototype is being compared with presently available units (Miller, 1973). These evaluations will provide data which will serve in advancing knowledge in the emerging area of ultrasonic studies.

To complement the activities of the Biomedical Application Teams, the Technology Utilization Office also sponsors a variety of biomedical engineering application projects at medical research centers around the country. A number of these are directly related to cardiovascular research. The NASA funding of these application projects has produced significant developments in the attack against heart disease, including advancements in pacemaker technology.

The rechargeable cardiac pacemaker. The natural pacemaker of the heart is the sinu-arterial node from which a wave of contraction spreads through the heart muscle with each beat. When the natural heartbeat fails or becomes irregular because of heart disease, an artificial pacemaker which delivers small, regular electric shocks can be life-saving. In the United States, approximately 30,000 pacemakers are implanted each year; another 30,000 units are implanted each year in the rest of the world (McClure, 1972).

The average life expectancy for pacemakers up to now has been about twenty-two months, after which time their mercury cell power supply is depleted. A surgical operation is then required to remove the pacemaker and implant a new device. Obviously, this repeated surgery can be traumatic, as can be the expense incurred. Payments under Medicare, for example, typically exceed \$2,000 for each pacemaker replacement.

Another disadvantage of these units is that their relatively large size and weight cause discomfort and prevent hiding the device cosmetically in patients, especially small children and persons with thin skin.

Scientists and doctors at the Johns Hopkins University Applied Physics Laboratory have developed, under the partial sponsorship of NASA, a new heart pacemaker which is rechargeable and much smaller than conventional units (see Figure 6). The new equipment uses electrical and electronic components first designed by NASA for use in spacecraft (NASA, 1973).

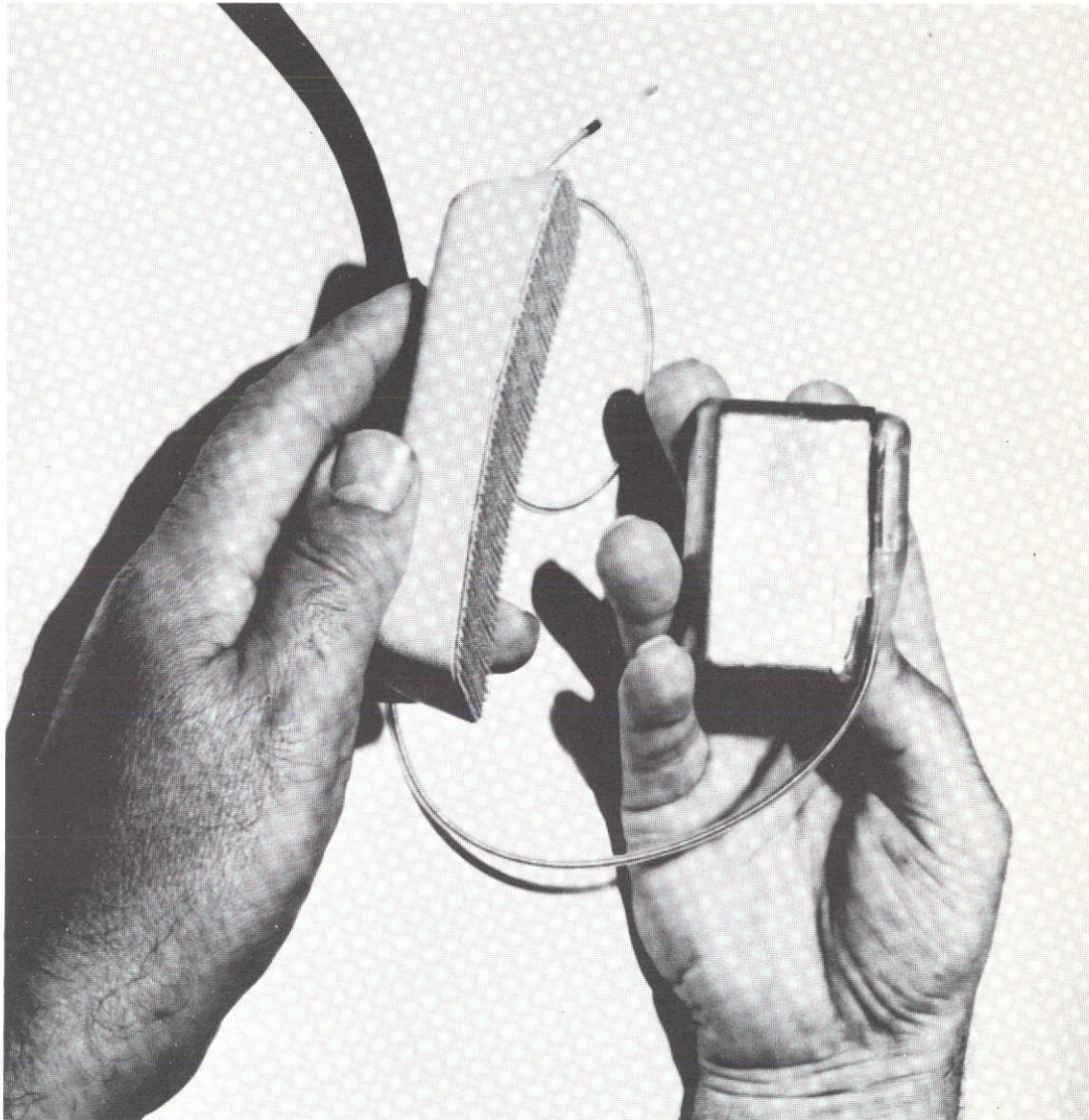


Figure 6. The Rechargeable Cardiac Pacemaker (Right),
Shown with Recharging Unit (Left).

The new device eliminates the need for frequent replacement by using rechargeable nickel-cadmium cells which are the result of many years of development for spacecraft applications. For ninety minutes each week the patient puts on a special vest that recharges the pacemaker battery by an alternating magnetic field transmitted through the skin, with no harmful effects (see Figure 7). Since it is recharged weekly, only one cell is required, and the size of the pacemaker can be reduced to half the thickness and 25 percent the volume of previously available models.

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Figure 7. Patient Wearing Vest to Recharge Pacemaker.

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Another advantage of the newly developed device is that it is immune to electrical interference sources, such as microwave ovens, car ignitions, and radars, that sometimes stop conventional pacemakers from operating.

Even with the rechargeable pacemaker being commercially available, work is continuing to improve pacemaker technology. NASA is providing technical and financial support for the utilization of the most advanced techniques of miniaturized, hybrid, solid state circuitry, as derived from spacecraft applications. This research will further reduce the size of the pacemaker and increase its reliability (McClure, 1972).

Conclusion

This brief examination of NASA contributions to the field of cardiology provides a unique perspective for understanding some of the larger issues involved in technology transfer. This document has described a number of NASA innovations that have broadened both the knowledge and the technology base of cardiology. In the aggregate, the significance of NASA's activities in cardiology can be found in the Agency's systematic approach to capturing, refining, and preserving technological gains of marginal interest to the mainstream of aerospace science, engineering, and flight requirements, but of great interest in terms of improving the quality of health care.

The point to be made here is that few of these innovations, in their initial form, can be expected to enjoy sustained and widespread use. This is because of the course of development of medical technology and its subsequent introduction into the marketplace. This course of development consists of: (1) initial research, development, evaluation, and prototype testing; (2) limited clinical testing and evaluation, with continual refinement; and (3) gradual introduction into routine clinical practice in several locations. It is only after these three phases are completed that a new device or technique finds its way into general use (Jones, 1966).

The rate of progression through these three phases depends upon the fundamental medical technology involved in the innovation. For rapid progression, the innovation must be based on technology that is widespread and presently understood by a majority of the practicing

medical profession. If the innovation involves new medical technology, the progression will be slow because of the educational time required to incorporate such technology into general practice.

Further, it is the medical profession which must finally carry an innovation through this progression. The essential consideration for NASA is that relevant aerospace R&D results have been transformed and made available to the community charged with responsibility for progress in combating heart disease. As such, the innovations provide new alternatives and focus for professional progress in the field.

In fact, this is the usual way in which the results of NASA R&D impact industrial, commercial, and public interests that lie outside aerospace. Rapid and intact adoption of any innovation occurs only when there is a lack of activity in the field, a vacuum. In application areas where there is strong professional and commercial activity, there is no vacuum. Thus, it is the "know how" embodied in aerospace innovation that most often represents an opportunity for improvements, not the specific innovation. This case study has examined only one arena in which that "know how" is transferring to a user community as a direct result of NASA's commitment to the secondary use of aerospace technology.

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